

REMARKS

Claims 1-9, 11-15, 17, 18, 20-48, 50, 52-73, and 75-80 are now pending in the application. Claims 10, 49, and 51 are canceled by this amendment. New Claim 80 is added by this amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

APPLICANT INITIATED INTERVIEW REQUEST

Applicants file this Amendment with a Request for Continued Examination. Applicants also, therefore, formally request an interview with the Examiner prior to any further Office Action and request that a preliminary amendment be considered, if all of the claims in the current amendment are not in condition for allowance, prior to any further Office Actions.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-15, 17-18, 22-30, 33-44, 47-73 and 77-79 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley et al. (U.S. Pat. No. 6,226,548) in view of Ellis (U.S. Pat. Pub. No. 2003/0011624). Claims 20, 21, 31, 32, 45, 46, 75, and 76 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley et al. (U.S. Pat. No. 6,226,548) in view of Ellis (U.S. Pat. Pub. No. 2003/0011624), and further in view of Acker et al. (U.S. Pat. No. 6,332,089) These rejections are respectfully traversed.

Initially, we note that Foley et al. is directed to a surgical navigation system with image guided technology. See col. 9, lines 27-31 and col. 11, Ins. 9-11. Images can be

acquired of the spinal elements 100, which are the vertebrae. Foley et al. discloses that additional screws can be placed in the vertebrae adjacent to the vertebrae containing the clamp and post prior to scanning. The image of the additional screws also shows in this scan. The image of the screw can then be compared to the actual position of the screw as indicated by a pointer probe that is touched to the head. See col. 9, lines 58-63. A probe can be used to adjusted a screw head, which can also be used to indicate the location and orientation of the screw head to the computer. See col. 10, lines 43-55.

Ellis is directed to a navigation system that morphs atlas image data to a patient, either with images or without, to assist in a guided procedure. See, Ellis abstract and para. [0072]. Ellis discloses that a bone portion is identified with multiple points that are touched. See, Ellis para. [0004] – [0005]. Ellis further discloses shortcomings of an imageless system, thus allowing the use of morphed atlas information to assist in the shortcomings. See, Ellis para. [0016].

Finally, Acker et al. is directed to a system including an intrabody probe. A site probe is affixed in the patient's body at the position to be treated. See, Acker et al. col. 12, Ins. 24-27. Acker et al. describes that a bold arrow or indicia can indicate the position of the instrument probe to the site probe. See, Acker et al. col. 12, Ins. 47-50 and col. 20, Ins. 9-53. Acker et al. does not appear describe an implanted or implantable member, system, or other elements.

Initially, Applicants submit that the combination Foley et al. and Ellis is not proper as submitted by the Office. The Office Action states that while Foley et al. is directed to an image based system, Ellis describes that an imageless system is an equivalent paradigm and can be substituted. Applicants respectfully submit, however, that while

Ellis discloses that imageless systems exist, Ellis also discloses that they are vastly different from image based systems. Moreover, Ellis discloses that there are deficiencies in the imageless systems that are not present in image based systems, such as the lack of all image information. See, Ellis para. [0016]. Foley et al. does not have these deficiencies at least because Foley et al. discloses an image system. Accordingly, the combination of Ellis and Foley et al. can **not** disclose an imageless system for use with Foley et al.

Contrary to the art cited in the rejections, however, Claim 1 recites, “a first member and a second member of the construct adapted to selectively interact with each other after implantation and operable to be fixed into a boney structure; a third member positionable relative to said first member and said second member in an anatomical portion; a first localization element fixed to said first member and a second localization element fixed to said second member; . . . wherein said processor is operable to receive position information for both of said first member, said second member, and said third member from said detector and further operable to determine a relative position between all of said first member, said second member, and said third member; . . . wherein said processor is operable to allow navigation of said third member relative to at least one of said first member or said second member in a substantially patient imageless manner wherein said first localization element remains fixed to said first member and said second localization element remains fixed to said second member while said third member is navigated.” The cited art, however, fails to anticipate or fairly render obvious at least the localization elements fixed to a first and second member

while navigating a third member. Accordingly, Claim 1, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

Claim 22 recites, “[a] first member including a bone engaging portion for fixation to a boney structure; a tracking element interconnected with the first member operable to be used to determine a position of the first member; . . . a navigable instrument operable to move the second member relative to the first member; and a second detector to detect said navigable instrument; wherein the tracking element remains connected to the first member during the movement of the navigable instrument; . . . wherein said processor is operable to navigate said navigable instrument relative to said tracking element for positioning of the second member relative to the first member in a substantially patient imageless display.” As discussed above, the cited art does not anticipate or fairly render obvious a system operable to navigate with an imageless display or a tracking element that remains attached during navigation. Accordingly, Claim 22, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

Claim 33 recites, “determining a position of the first member in a selected space with a first tracking element connected to the first member ; . . . determining a position of the second member in the selected space with a second tracking element connected to the second member; navigating the third member relative to the first member and the second member, while maintaining the first tacking element connected with the first member and maintaining the second tracking element connected to the second member, . . . displaying an icon to represent the position of at least two of the first member, the second member, or the third member in a substantially patient imageless

manner.” As discussed above, the cited art does not anticipate or fairly render obvious a method including determining a position with two tracking elements and maintaining their attachment while navigating a third or displaying icons in an imageless manner. Accordingly, Claim 33, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

Claim 53 recites, “displaying said position of each of said first member and the second member as two or more icons on a display; . . . navigably positioning at least one of said first member, said second member, or said third member relative to another of at least one of said first member, said second member, or said third member to achieve the selected final orientation with assistance of said icons; displaying an additional icon relative to the two or more icons to illustrate a position of at least one of said first member, said second member, or said third member in a substantially patient imageless manner.” Applicants respectfully submit that the art cited in the rejections fails to anticipate or fairly render obvious a method to navigably position members with the assistance of icons in an imageless manner. Accordingly, Claim 53, and each of the claims that depend directly indirectly therefrom, is in condition for allowance.

Claim 67 recites, “a tracking element attached to a moveable head of the first member to assist in determining a position of the first member; . . . a navigable instrument operable to move the second member relative to the first member while the first member is fixedly implanted into a boney structure of an anatomy with the tracking element attached thereto; . . . wherein the display is operable to illustrate the first icon and the second icon in a substantially patient imageless manner for navigation of the first member relative to the second member. As discussed above, the cited art does not

anticipate or fairly render obvious a system having a tracking element attached to a member fixedly implanted and an instrument operable to move a second member relative to the first member while the tracking element is attached. Accordingly, Claim 67, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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